

DATE OUT:

SUBJECT: STORAGE STABILITY (830.6317) & CORROSION CHARACTERISTICS
(830.6320) REVIEW
ACCELERATED STUDY ☐; ONE YEAR STUDY ☒;
OVER 1 YEAR STUDY ☒
MP ☐ EP ☒ EUP ☐
DP BARCODE No.: 355992 REG. No.: 72056-2
DECISION No.: 399383 MRID No(s): 475162-01
PRODUCT NAME: CLETHODIM 2EC HERBICIDE
COMPANY: NISSO BASF AGRO CO., LTD.

FROM: William Herald / Reviewer
Product Chemistry Team
Technical Review Branch/RD (7505P)

TO: James Stone / Joanne Miller, RM 23
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I. CONCLUSIONS:

STORAGE STABILITY (830.6317):
☐ ACCEPTABLE
☐ UNACCEPTABLE*
☒ UPGRADEABLE*

40CFR158.190 DATA REQUIREMENT: ☐ SATISFIED ☒ NOT SATISFIED

CORROSION CHARACTERISTICS (830.6320):
☐ ACCEPTABLE
☐ UNACCEPTABLE*
☒ UPGRADEABLE*

40CFR158.190 DATA REQUIREMENT: ☐ SATISFIED ☒ NOT SATISFIED

* If unacceptable or upgradeable describe the deficiency and provide recommendations

Comments & Recommendations:

Registrants' label recites 26.4% for the AI. In the study the initial quantitative result of the test substance shows a concentration of the AI at 25.5% in the test substance; this is an amount that is below the allowed lower limits recited in Title 40 USCFR § 158.350. Registrant should edit the label to more accurately reflect the amount of AI% contained in the test substance and is within the statutory parameters required in Title 40 USCFR § 158.350.

II. STUDY SUMMARY

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A. STUDY CONDUCTED UNDER US GLP/OECD GUIDELINES

☒ Yes

☐ No

B. PRODUCT INFORMATION

Active ingredient: Clethodim.

Label claims Nominal concentrations (%): 26.4.

Initial concentration(s) of the AI(s) (%) used in the study: 25.5% PYROXSULAM.

Lower certified limits (%) based on AI % in the study: 24.735% PYROXSULAM.

C. EXPERIMENTAL PARAMETERS

Temperature: Ambient laboratory temperatures ranging between 18°C to 24°C.

Duration of study: ☒ 1 year; ☐ over 1 year

Type of container: Sponsor provided 8oz white, Fluorinated HDPE, F-style bottle with Fluoro-seal level 3 fluorine treated cups with caps made of Rexam closures with 28 mm-400 white induction heat seal liner.

Analysis at intervals: ☒ 0 (initial); ☒ 3 months; ☒ 6 months;
☒ 9 months; ☒ 12 months

D. ANALYTICAL METHOD

Method	DETECTOR
High Pressure Liquid chromatography (HPLC)	UV/VIS (290nm)

E. RESULTS

The report shows that following the initial characterization of the AI:

- 1) Based on the Initial concentration of the AI used in the study, after storage at ambient laboratory temperatures ranging between 18°C to 24°C for the testing intervals at 3, 6, 9 and 12 months, the AI% remained well within statutory parameters required in Title 40 United States Code of Federal Regulations § 158.350. However, registrants' label recites 26.4% for the AI; and the initial quantitative analysis of the test substance shows a concentration of the AI below the allowed lower limits recited in Title 40 USCFR § 158.350. It is suggested that registrant edit their label to more accurately reflect the amount of AI% contained in the test substance.
- 2) There were no reported adverse reactions involving the 8oz HDPE containers with the pale brown, oily liquid test substance at any point of the 12 month study. There were no signs of discoloration, clumping or phase separation of the test substance. The containers showed no signs of cracking, fogging, discoloration or distortion. The maximum total percent weight change of the container containing the test substance was $\pm 0.01\%$.